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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

CORCEPT THERAPEUTICS, INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

Civil Action No. 1:18-cv-03632
(RMB)(LDW)

Filed Electronically

TEVA'S RESPONSIVE POST-TRIAL BRIEF

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I. Corcept’s brief confirms that it failed to show specific intent to induce infringement.

To induce infringement of a method patent, one must encourage every single step in the method. *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1219 (Fed. Cir. 2014). Here, the claimed methods all require co-administration of mifepristone with a strong CYP3A inhibitor; therefore, to prove inducement, Corcept must prove that Teva encourages co-administration. But instead of encouraging co-administration, Teva’s label warns against it. Teva Br. 11–12. Therefore, Teva’s label does not induce infringement. To be sure, Teva’s label recommends *how* to adjust the mifepristone dosage *if* such co-administration occurs. But the Federal Circuit’s decision in *HZNP Medicines LLC v. Actavis Lab’ys UT, Inc.* forecloses a finding of specific intent to induce infringement where, as here, the product label describes but does not encourage infringing use. 940 F.3d 680, 702 (Fed. Cir. 2019).

In *HZNP*, defendant Actavis’s label instructed users to apply diclofenac sodium to the knee for osteoarthritis pain and to “[w]ait until area is completely dry before ... applying sunscreen [or] insect repellant” *Id.* at 699–700. These statements were held *not* to induce infringement of claims requiring (i) applying diclofenac sodium to the knee, (ii) waiting for the treated area to dry, and (iii) applying sunscreen or insect repellant. *Id.* at 700–02. That is because, although the label described application of sunscreen or insect repellent, it did not encourage that step. The label warning “operate[d] in an ‘if/then’ manner: *if* the user wants to cover the treated area with clothing or apply another substance over it, *then* the patient should wait until the area is dry.” *Id.* at 702. Teva’s label similarly describes administration of mifepristone with a strong CYP3A inhibitor, but it does not encourage that step. Teva’s label operates in an if/then manner: *If* the physician elects to use mifepristone with a CYP3A inhibitor, *then* the physician should adjust the mifepristone dosage.

Rather than arguing that Teva’s label encourages co-administration, Corcept suggests (at

14–16) that *HZNP* cannot mean what it says about statements in if/then format not inducing infringement because a physician is always free not to prescribe a medicine or not to follow the instructions on the label. But that is not the relevant inquiry for inducement. The question is: Does *the label* encourage each step of the patented method? Here, the answer is no: a doctor administering Korlym and following the label is never advised to co-administer with a strong CYP3A inhibitor. Indeed, Dr. Carroll has never co-administered despite prescribing mifepristone for 11 years. Tr. 266:9–12, 266:18–23, 273:17–19.

Corcept argues (at 17) that when it is medically necessary to co-administer, the dose adjustments on the label are not optional and will sometimes lead to infringing use. But there are two problems with this argument. First, if a doctor decides to co-administer, that decision will not be based on anything in Teva’s label, which says nothing about when co-administration might even be beneficial, let alone necessary. Second—and more fundamentally—the Federal Circuit in *HZNP* already considered and rejected the same argument. Horizon argued that “application of sunscreen” was sometimes “medically necessary” and that, “when such need arises, Actavis’s instruction will lead to an infringing use.” 940 F.3d at 701. The court rejected this logic and held that the “mere existence of direct infringement ... is not sufficient for inducement.” *Id.* at 702 (quoting *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631). As in *HZNP*, the fact that Teva’s label does not require co-administration reflects that its product has “substantial noninfringing uses” so that “intent to induce infringement cannot be inferred” even if Teva is aware that some users may infringe. *Id.* (quoting *Warner-Lambert v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003)).¹ Indeed, Teva’s defense here is stronger

¹ Corcept cites *Sanofi v. Watson Lab’ys Inc.* to argue that substantial noninfringing uses do not preclude a finding of inducement. But *Sanofi* is the inverse of this case: there, although the drug had “substantial noninfringing uses not forbidden by the proposed labels,” the label

than in *HZNP* because instead of merely being silent on co-administration, the label warns against it.

II. Corcept's brief confirms that it failed to show direct infringement.

“Determining what will, or would, happen when a product enters the market requires “consideration of all the relevant evidence,” including the proposed label’s instructions “*and physician practice.*” *Genentech, Inc. v. Sandoz Inc.*, 55 F.4th 1368, 1380 (Fed. Cir. 2022) (citing *Ferring v. Watson Lab’ys*, 764 F.3d 1401, 1408 (Fed Cir. 2014)) (emphasis added). Corcept relies (at 5–6) on *Par Pharm., Inc. v. Eagle Pharm.*, 44 F.4th 1379 (Fed. Cir. 2022), to argue that the ANDA alone controls the infringement inquiry. But the issue in *Par* was whether defendant’s ANDA product met the claimed pH, and the ANDA was dispositive because it set forth the key pH data. *Id.* at 1384. By contrast, the claims here are method claims, so evidence of physician practice is relevant to determine whether anyone will ever perform the methods. Yet Corcept has failed to come forward with even a single example of anyone doing so.

Having failed to show past direct infringement, Corcept states (at 2–5) that Teva’s label alone is sufficient to show future direct infringement. But there is no reason to think (and no evidence suggesting) that Teva’s label will cause physicians to practice the claimed methods when Korlym’s identical label has not. Corcept erroneously assumes that doctors who prescribe mifepristone will inevitably find it necessary to co-administer strong CYP3A inhibitors. But the evidence does not support that assumption. Dr. Snyder testified that it would never be medically necessary to administer these drugs together and that the risks of co-administration outweigh the

actually encouraged the infringing use. 875 F.3d 636, 646 (Fed. Cir. 2017). Here, by contrast, although the label does not forbid infringing uses, the label encourages only noninfringing uses, which (as *HZNP* and *Warner-Lambert* explain), avoids liability for inducement.

benefits.² Tr. 410:9–22. Dr. Carroll testified that those who would receive mifepristone and a strong CYP3A inhibitor either have very high cortisol levels or suffer from an infection. Tr. 229:12–22, 238:4–13. But neither condition makes co-administration based on the label likely. As for high cortisol levels, Dr. Carroll admitted that the label does *not* state or suggest that combination therapy is more effective than mifepristone alone. Tr. 299:22–300:2. Co-administration “would be the decision of the provider,” not based on the label. Tr. 299:16–17. As for infections treated with CYP3A inhibitors, Dr. Carroll pointed to aspergillosis as an example. But he admitted that Teva’s label does not mention aspergillosis. Tr. 292:24–293:1. He acknowledged that UpToDate (JTX-22) provided reasons *not* to use itraconazole when treating aspergillosis. Tr. 296:19–23. And he did not know of *any* type of infection that can be treated only with ketoconazole or clarithromycin. Tr. 298:11–13, 17–19. In short, another (non-strong-CYP3A-inhibitor) option is always available. So doctors will likely never need to co-administer.

Corcept also wrongly assumes that physicians who co-administer will infringe. But, as the Court correctly observed, the patents require more than mere co-administration. Tr. 493:10–16. And the evidence shows that a physician can follow Teva’s label and never infringe, as the label has instructions for co-administering that will not result in infringement. Teva Br. 13–14.

Corcept argues (at 19–20) that claim 6 is different from the other asserted claims because administering mifepristone to a patient *already* taking a strong CYP3A inhibitor does not count as co-administering the drugs. Corcept’s position cannot be squared with the claim language,

² Corcept repeatedly takes Dr. Snyder’s statements out of context and mischaracterizes them. For example, Corcept says (at 18), “He does not believe Teva’s label even encourages the administration of mifepristone by itself”—falsely implying that he said the label does not encourage using mifepristone at all. In context, however, Dr. Snyder simply pointed out that the label gives instructions on administering mifepristone but does not expressly say only to use the drug alone or as “monotherapy.” Tr. 420:16–421:11.

prosecution history, or Dr. Belanoff's testimony. Teva Br. 2 n.1. In any event, claim 6 requires giving 900 mg of mifepristone to such a patient. Teva's label requires the dose to start at 300 mg and then titrate slowly upward only if clinically necessary in the prescriber's judgment. But there is no evidence that anyone would give a dose as high as 900 mg when co-administering.

Regarding dosages actually being taken, Corcept boldly states (at 10) that "over 750 patients receive[] a 900 or 1200 mg dose [of mifepristone]." This statement finds zero support in the record; there was no evidence of the number of patients actually receiving any given dose. Instead, Dr. Belanoff testified that patients in the 2009 SEISMIC study received 900 mg or more. Yet the SEISMIC study involved only 34 subjects (not 750) and tested a variety of doses. The study did not involve co-administration, and so cannot show direct infringement. Teva Br. 7–8; PTX-051.38. Corcept also cites a page plucked from FDA's 2012 Medical Review for Korlym, PTX-051.107, that was never mentioned at trial.³ That page discloses that a subset of the 34 subjects from the SEISMIC study participated in a follow-on study with mifepristone doses as high as 1800 mg (150% of today's maximum approved dose)—again, without CYP3A inhibitors. PTX-051.48, .107. But the number of patients who took high doses of Korlym alone in a clinical trial in 2009 tells nothing about the starting or ending dosage of mifepristone in patients who also receive a strong CYP3A inhibitor. Corcept has simply failed to adduce evidence that physicians will co-administer mifepristone and a strong CYP3A inhibitor at the claimed doses and in the claimed order.

CONCLUSION

Teva respectfully requests the Court enter judgment that Teva does not infringe the '214 and '800 patents.

³ Corcept used PTX-051 at trial because the exhibit mentions co-administration, not because it has information about actual prescribing practices (which it does not have).

Dated: November 9, 2023

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